

Application No. 10/511,527

Reply to Office Action

*REMARKS/ARGUMENTS***RECEIVED**
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AUG 09 2006*Restriction Requirement*

The Office Action has set forth a restriction requirement. Applicants elect, with traverse, the claims of Group I (claims 1-16), polymorphic sequences D7S522, D8S256, and D16S400 of claim 6. Reconsideration of the requirement for restriction is respectfully requested for the reasons discussed below.

*Discussion of the Restriction Requirement*Unity of Invention

The restriction requirement is traversed because the pending claims, including claim 6 reciting polymorphic sequences, relate to "one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT § 13.1. The inventive method does not depend on a specific set of polymorphic sequences. Instead, the subject matter of all of the pending claims relates to a single general inventive concept, that concept being the sampling and analyzing of cell clusters as a preferred material for the detection and characterization of tumors (see, e.g., page 6, lines 12-13 and page 8, lines 11 to 17). Such cell clusters are superior for tumor detection and staging. As stated in the specification, "[t]he degree of malignancy, the invasiveness in affecting other organs, and the formation of metastases can be determined with this innovative method by genotyping cells from cell cultures." See page 6, lines 7-9. The single inventive concept of isolating and analyzing cell clusters to detect and characterize primary tumors and separate areas of primary tumors is common to all of the pending claims. Thus, the restriction requirement, based on PCT § 13.1, is inappropriate.

Undue Burden

Further, the restriction requirement is traversed for being improper. There are two criteria for a proper requirement for restriction between patentably distinct inventions: (i) the inventions must be independent or distinct as claimed, and (ii) there must be a serious burden on the Examiner if restriction is not required. M.P.E.P. § 803. Consequently, as set forth in M.P.E.P. § 803: "If the search and examination of all the claims in an entire application can

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be made without serious burden, the examiner must examine them on the merits, even though they include claims to distinct or independent inventions.”

In addition, “the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required ... [and] must show by appropriate explanation one of the following: (1) separate classification thereof ... (2) a separate status in the art when they are classifiable together ... (3) a different field of search.” M.P.E.P. § 808.02. Here, the Office has failed to show any separate classification, separate status in the art when classifiable together, or a different field of search for the claimed subject matter. “Where ... the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.” M.P.E.P. § 808.02.

Thus, because the Office Action does not indicate, let alone establish, that there would be a “serious burden” on the Examiner to examine all of the polymorphic sequences of claim 6 at the same time, the restriction requirement is improper. Indeed, since the polymorphic sequences of claim 6 relate to a method for the detection and characterization of primary tumors and separate areas of primary tumors, it would appear that there would be no “serious burden” on the Examiner in addressing the polymorphic sequences of claim 6 at one time. In the absence of such a “serious burden,” the restriction requirement is improper even if groups of claims are drawn to distinct or independent inventions.

Furthermore, Applicants note that the restriction does not affect the examiner's search of independent claim 1. The Office's search for prior art relating to the single inventive concept of the pending claims does not hinge on the polymorphic sequences recited in the dependent claims. As such, there can be no serious burden on the examiner to search and examine the unifying inventive concept reflected in claim 1 and all claims dependent thereon.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the

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prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Salim A. Hasan', is written over a horizontal line.

Salim A. Hasan, Reg. No. 38,175
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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